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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,340	08/01/2001	Leonard W. Kaplan	9500-0001	4115

23980 7590 09/10/2002

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/10/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,340

Applicant(s)

KAPLAN ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-55 and 75-116 is/are pending in the application.
- 4a) Of the above claim(s) 80-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-55, 75-79 and 84-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction requirement submitted August 5, 2002 is acknowledged. Applicant's election therein of the invention of Group II, claims 51-55 and newly added claims 75-116, and the species mometasone furoate and pirbuterol acetate are acknowledged.

Election is considered to have been made **without** traverse in Paper No. 7, because no traversal or reasons for traversal have been stated.

Claims 80-83 are withdrawn as being drawn to non-elected species. Claims 51-55 and 75-79 and 84-116 are herein examined on the merits in so far as they read on the elected species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 51-55, 75-79 and 84-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sequiera et al. (USPN 5,837,699) in view of Maxair inhaler in PDR.

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Sequiera et al. (USPN 5,837,699) teaches a method of treating allergic and/or inflammatory diseases of the lower airway passages and/or lungs such as asthma and rhinitis by administering the corticosteroid mometasone furoate (anhydrous mometasone furoate or mometasone furoate momhydrate) intra-nasally or via oral inhalation, see col. 2, lines 20-54, col. 3, lines 24-50, col.5, line 55-56. Sequiera et al. (USPN 5,837,699) further teaches that mometasone furoate can be employed as adjuvant therapy with bronchodilators, see col. 5, lines 5-17. Sequiera et al. (USPN 5,837,699) also teaches the incorporation of its formulation into dry-powder aerosolized metered-dose inhaler in which propellants such as chlorofluorocarbons, non-chlorofluorocarbons and fluorocarbon, pharmaceutically acceptable carrier such as lactose are

employed at a dosage of 10-5000 mcg/day, see col. 5, lines 18-45, see also claims 3-21.

Sequiera et al. (USPN 5,837,699) teaches that its formulations can also be administered in the form of an aqueous suspension with conventional pharmaceutical excipients at a dose of 50-1600 mcg/day, see col. 10, lines 7-22 and col. 5 line 46-col. 6 line 18.

Sequiera et al. (USPN 5,837,699) does not particularly teach the incorporation of pirbuterol acetate in its composition employed in a method of treating allergic and/or inflammatory diseases of the lower airway passages and/or lungs such as asthma and rhinitis. Neither does Sequiera teach the incorporation of its pharmaceutical composition into a capsule.

Maxair inhaler in PDR teaches a pirbuterol acetate bronchodilator aerosol, a known beta-2 adrenergic receptor agonist, employed in a method of treating asthma and preventing bronchospasm at a dosage of 200-400 mcg/day. Maxair inhaler in PDR also teaches that its inhaler can be employed concurrent with steroid therapy.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ pirbuterol acetate in a composition comprising the corticosteroid mometasone furoate, employed in a method of treating allergic and/or inflammatory diseases of the lower airway passages and/or lungs such as asthma and rhinitis.

One of ordinary skill in the art would have been motivated to employ pirbuterol acetate in a composition comprising the corticosteroid mometasone furoate, employed in a method of treating allergic and/or inflammatory diseases of the lower airway passages and/or lungs such as asthma and rhinitis because both mometasone furoate and pirbuterol acetate are known to be employed in treating allergic and/or inflammatory diseases of the lower airway passages and/or lungs such as asthma and rhinitis. combining two agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Optimization of amounts and intra-conversion of dosage forms are within the skill of the artisan and are therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

RUSSELL TRAYZAS
PRIMARY EXAMINER
GROUP 1200

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Mojdeh Bahar
Patent Examiner
September 5, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200
